

FOOD & BEVERAGE LITIGATION UPDATE



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LEGISLATION, REGULATIONS AND STANDARDS

New York Lawmaker Questions Industry on Livestock Antibiotic Use

U.S. Representative Louise Slaughter (D-N.Y.) has sent a [letter](#) to more than 60 food producers and retailers, "asking them to disclose their policies on antibiotic use in meat and poultry production." Citing "decades of research," the February 16, 2012, letter claims that agricultural antibiotic applications have contributed to drug-resistant disease in humans and seeks to clarify "the extent to which the fast food industry sources its meat and poultry from companies that routinely use antibiotics to raise livestock."

Slaughter, the only microbiologist in Congress, is soliciting information from retailers about their meat and poultry purchasing practices, as well as any efforts to educate consumers about the antibiotics used during food production. In particular, the letter directs recipients to provide details about whether their beef, pork and poultry supplies were produced (i) "without any antibiotics"; (ii) "in a manner that includes antibiotics only for disease treatment"; (iii) "in a manner that includes antibiotics only for treatment and control of disease"; or (iv) "in a manner that includes the routine use of antibiotics."

"Very simply, consumers have a right to know what's in their food," Slaughter stated in a concurrent press release. "The U.S. is facing a growing public health crisis in the form of antibiotic-resistant bacteria, and information about how these companies are contributing to its rise or resolution should be available to consumers."

To bolster this argument, Slaughter has also pointed to a recent study explaining how livestock antibiotic use allegedly gave rise to a strain of methicillin-resistant *Staphylococcus aureus* (MRSA) known as MRSA CC398. Lance B. Price, et al., "*Staphylococcus aureus* CC398: Host Adaptation and Emergence of Methicillin Resistance in Livestock," *mBio*, February 2012. Led by the Translational Genomics Research Institute (TGen), scientists from 20 collaborating organizations apparently used whole genome sequencing "to trace the likely history of MRSA CC398," according to a February 21 TGen press release.

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Relying on 89 human and animal genomes from 19 countries and four continents, the study's authors focused on MRSA CC398 as "a rapidly emerging cause of human infections, most often associated with livestock exposure." Their results reportedly suggested that MRSA CC398 "started as a non-resistant (antibiotic-susceptible) strain in humans before it spread to food animals where it subsequently became resistant to several antibiotics," including tetracycline and methicillin, "likely as the result of the routine antibiotic use that characterizes modern food-animal production."

In response to these findings, Slaughter issued a February 21 press release highlighting her efforts to pass The Preservation of Antibiotics for Medical Treatment Act (PAMTA). "We know that the routine use of antibiotics in livestock can create antibiotic-resistant bacteria that can kill humans," she concluded. "This discovery eliminates all cause for delay—we must raise our livestock in a responsible and sustainable way. Every day that we continue the routine use of antibiotics on healthy animals is another day we encourage the growth of deadly superbugs."

Dioxin Reassessment Finds Low-Dose Exposures Persist Without Significant Health Risk

The U.S. Environmental Protection Agency (EPA) has issued its non-cancer [dioxin reassessment](#) 27 years after the ubiquitous chemical was last assessed and has established a consumption limit of 0.7 picogram of dioxin per kilogram of body weight per day. The agency has found that, while low-dose exposures persist, primarily from the consumption of meat, fish and other animal products, and ultra-low levels of exposure can pose health risks, "current exposure to dioxins does not pose a significant health risk" over a lifetime, given significant reductions in industrial dioxin emissions.

According to EPA, air emissions of the chemical from industrial processes have been reduced 90 percent since the 1980s, but it breaks down slowly and remains in the water and soil to be consumed by fish and livestock feeding on contaminated plants. Most ambient dioxin today is apparently a result of backyard trash burning. The non-cancer health effects examined in this part of the dioxin reassessment, purportedly the result of large exposures from accidents or significant contamination events, are chloracne, "developmental and reproductive effects, damage to the immune system, interference with hormones, skin rashes, skin discoloration, excessive body hair, and possibly mild liver damage." EPA intends to release a cancer reassessment at a later date.

Environmental activists reportedly lauded the reassessment, but questioned EPA's minimal risk conclusion because some people have higher exposures or are more vulnerable to potential health effects than others. According to one scientist, fetuses, nursing babies and those with suppressed immune

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systems, such as AIDS patients and transplant recipients, are more sensitive to dioxin exposure. Industry interests called the draft reassessment on which the document is based “scientifically flawed” and claimed that EPA overstated the risks because exposures are now exceptionally low. *See EPA News Release and Environmental Health News*, February 17, 2012.

FDA to Review Safety and Legality of Inhalable Caffeine

According to Senator Charles Schumer (D-N.Y.), the Food and Drug Administration (FDA) has agreed to investigate the safety and legality of AeroShot®, which allows consumers to inhale a powder delivering 100 mg of caffeine to the body. Created by a Harvard professor and a company led by Harvard graduate Tom Hadfield, the product was apparently launched in January 2012 in New York and Boston markets. Its sale is not limited by any age restrictions nor has the product been reviewed by any agency. Still, Hadfield has reportedly indicated that the FDA review “will conclude that AeroShot is a safe, effective product that complies with FDA regulations.”

Schumer called for the FDA review in a December 2011 letter raising concerns about the use of caffeine by children and adolescents. He also noted that a company marketing video “flashes through a variety of settings, including a dance party, a club scene, and a bar, where users are shown with AeroShot inhalers in their mouths. . . . This new inhalable caffeine product seems well on its way to being marketed to encourage use by young adults in conjunction with alcohol.” Schumer also said, “We need to make sure that AeroShot does not become the next Four Loko by facilitating dangerous levels of drinking among teenagers and college students.” *See Press Release of Senator Charles Schumer*, February 21, 2012; *npr.org*, February 22, 2012.

Meanwhile, the Illinois-based PapaNicholas Coffee Co. has reportedly launched Versanto Force 3X®, described as “a new, hyper-caffeinated coffee, a product with three times the caffeine of ordinary coffee.” The company offers the product in three flavors: “High Octane Premium,” “Supersonic Cinnamon,” and “Vortex Vanilla.” Sold in grocery stores for brewing at home, the coffee is marketed as a convenience to those seeking to avoid long lines in coffee shops and needing three standard cups of coffee to wake up in the morning. *See PR Newswire*, February 21, 2012.

FDA Issues Recordkeeping Guidance on Food Distribution

The Food and Drug Administration (FDA) has [issued](#) updated industry guidance “pertaining to the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food.” Although this [fifth edition](#) is effective immediately, FDA welcomes comments at any time.

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Requiring records that identify “immediate previous sources and the immediate subsequent recipients of food” along the food-distribution chain, FDA has been given expanded authority by the Food Safety and Modernization Act of 2011 to “access records relating to foods that may cause serious adverse health consequences or death to humans or animals.” Although the guidance incorporates these statutory changes, it has not deviated much from the fourth edition released in September 2006, FDA said. Rather, it provides practical information on such topics as records requirements, retention and availability, and “the consequences of failing to establish and maintain required records or failing to make required records available to FDA.” See *Federal Register*, February 23, 2012.

WHO Backs Publication of Controversial H5N1 Research

A meeting of World Health Organization (WHO) health experts has reportedly reached a [consensus](#) on whether to proceed with controversial avian influenza research despite potential security risks. WHO apparently convened the consultation after officials expressed concern about H5N1 strains modified in U.S. and Dutch laboratories to spread more easily among mammals. In particular, panelists discussed recommendations to redact two studies on the new viruses and implement “a mechanism for providing the restricted information to legitimate recipients.”

“Given the high death rate associated with this virus—60 percent of all humans who have been infected have died—all participants at the meeting emphasized the high level of concern with this flu virus in the scientific community and the need to understand it better with additional research,” said WHO Assistant Director-General of Health Security and Environment Keiji Fukuda in a February 17, 2012, press release. “The results of this new research have made it clear that H5N1 viruses have the potential to transmit more easily between people underscoring the critical importance for continued surveillance and research with this virus.”

To this end, the WHO panel approved continuing work on naturally occurring avian influenza but agreed to extend “a temporary moratorium” on research with the modified viruses. It also moved to delay publication pending “(1) a focused communications plan to increase public awareness and understanding of the significance of these studies and the rationale for their publication, and (2) a review of the essential biosafety and biosecurity aspects of the newly developed knowledge.” As Fukuda explained, “There is a preference from a public health perspective for full disclosure of the information in these two studies. However, there are significant public concerns surrounding this research that should first be addressed.”

Once these concerns have been addressed, the panel has urged the release of the new work without any redactions, a decision that reportedly worried

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National Institute of Allergy and Infectious Diseases Director Anthony Fauci, who attended the meeting on behalf of the United States. "The group consensus was that it was much more important to get this information to scientists in any easy way to allow them to work on the problem for the good of public health. It was not unanimous, but a very strong consensus," he was quoted as saying. *See The New York Times*, February 17, 2012.

OEHHA Extends Comment Period on Potential Prop. 65 Chemicals

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has [extended](#) the comment period for several chemicals, including benzophenone, a chemical used in plastic packaging as a UV blocker, that the agency is considering adding to the list of chemicals known to the state to cause cancer (Prop. 65) under the Labor Code mechanism. Public comments are now requested by March 22, 2012. According to OEHHA, "[b]ecause these are ministerial listings, comments should be limited to whether the International Agency for Research on Cancer has identified the specific chemical or substance as a known or potential human or animal carcinogen."

LITIGATION

Court Stays Illinois *Trans* Fat Litigation Against Quaker Oats

A federal magistrate judge in Illinois has stayed a putative class action, the fourth of five brought against The Quaker Oats Co., alleging that the company deceives consumers by representing that its granola and oatmeal products are "heart healthy," "wholesome," and a "smart choice made easy," when they actually contain *trans* fat. *Askin v. The Quaker Oats Co.*, No. 11-111 (U.S. Dist. Ct., N.D. Ill., E. Div., order entered February 15, 2012). The named plaintiff, a New York resident, filed his complaint on behalf of a putative nationwide class after other similar suits were filed in California, where they are proceeding as one consolidated action. He unsuccessfully sought to consolidate all of the action in Illinois before a multidistrict litigation court.

Quaker and the intervening plaintiffs, who filed the California actions, asked the court to dismiss the Illinois action under the first-to-file rule, and the court denied the request despite finding that the suits are virtually identical and that the first-to-file doctrine applies. According to the court, "even where suits are mirror-images, dismissal of the later-filed action is rarely the appropriate remedy," because dismissing a duplicative case could lead to statute of limitations problems. The movants apparently failed to present any arguments to assure the court that the Illinois plaintiff's rights would not be prejudiced if his case were dismissed outright. The court found persuasive the Illinois plaintiff's argument that the California plaintiffs would not succeed in certifying a nationwide class under California law because that state's consumer protection statute cannot apply to him or any other non-California residents.

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In this regard, the court stated, “If this court were to dismiss the current lawsuit and the California cases proceed to the outcome he predicts, there is a possibility that he will be foreclosed by the applicable statutes of limitations from pursuing the relief he seeks here, or at the very least, that the claims of some of the putative class members encompassed by the current proposed class definition will be foreclosed.” Accordingly, the court determined that staying the Illinois action “is the appropriate way to account for the first-to-file rule in this matter.” The case will be stayed “pending the outcome of the currently ripe motion to dismiss pending in California and, if the consolidated actions survive dismissal, the class certification decision in the California actions.”

Tomato Grower’s Negligence Claims from 2008 Recall Survive Motion to Dismiss

A federal court in South Carolina has reportedly determined that a tomato grower seeking damages from the U.S. Food and Drug Administration (FDA) allegedly caused by a 2008 tomato recall that followed a *Salmonella* outbreak which was ultimately found not to be linked to contaminated tomatoes, may pursue negligence claims against the agency. *Williams Farms Produce Sales, Inc. v. United States*, No. 11-01399 (U.S. Dist. Ct., D.S.C., order entered February 23, 2012). Further details about the case appear in [Issue 398](#) of this *Update*.

The court has apparently dismissed claims of defamation, slander of title, product/commercial disparagement, unconstitutional taking, and violation of unfair trade practices law. *See Law360*, February 23, 2012.

FDA and NRDC Reach Agreement in FOIA Records Dispute Related to BPA in Food Packaging

The Food and Drug Administration (FDA) and the Natural Resources Defense Council (NRDC) have agreed to a timeline for the production of material NRDC requested under the Freedom of Information Act (FOIA) involving bisphenol A (BPA) in food packaging and food contact materials. *NRDC v. FDA*, No. 11-8662 (U.S. Dist. Ct., S.D.N.Y., stipulation and order filed February 21, 2012). Additional information about the litigation appears in [Issue 420](#) of this *Update*.

The agreement narrows the request, limits the FDA offices required to conduct searches for responsive records and specifies the format in which the records will be produced. It also creates a timeline for FDA to produce internal material, material involving other agencies and a list of withheld documents. Any further proceedings in the litigation NRDC filed to force the agency to respond to its FOIA request are stayed until further order of the court on or after August 22, 2012. NRDC is obligated to notify the court and defense counsel by that date if it intends to challenge any withholdings or the adequacy of FDA’s search. In that event, a summary judgment briefing schedule will be provided to the court.

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NRDC has been seeking since 2008 to prohibit the use of BPA in food packaging, and, in an agreement reached in a separate lawsuit, the agency has committed to issuing a decision on NRDC's petition by March 31.

Starbucks Files Brief Seeking to Uphold Judgment in Tip Dispute

Starbucks Corp. has filed its response in the Second Circuit Court of Appeals in a dispute over tip sharing, asking the court to affirm the district court's grant of summary judgment in its favor. *Lawrence v. Starbucks Corp.*, No. 11-3199 (2d Cir., brief filed February 22, 2012). Additional information about related litigation involving Starbucks baristas and shift supervisors appears in [Issue 256](#) of this *Update*. The company asserts that the district court correctly held that (i) New York labor law does not grant plaintiff assistant store managers the right to participate in a tip pool, and Starbucks did not "demand," "accept," or "retain" their tips; (ii) Starbucks' policy of allowing only baristas and shift supervisors to share tips is consistent with state law; and (iii) assistant store managers exercise control over their subordinates' employment status and are thus "agents" prohibited from sharing tips under state law.

Prison Inmates Challenge Soy in Diet as Cruel and Unusual Punishment

Counsel for five current and former Illinois prison inmates has reportedly indicated that four expert witnesses are prepared to testify that the soy in the inmates' prison diets caused them "irreparable, actual harm," and thus their litigation against the state, prison wardens and nurses will proceed. *Harris v. Brown*, No. 07-03225 (U.S. Dist. Ct., C.D. Ill., filed August 16, 2007). According to a news source, the inmates are seeking an order to stop the Illinois Department of Corrections from using soy in the food prisoners eat; the plaintiffs claim they consumed up to 100 grams of soy protein daily despite Food and Drug Administration recommendations that soy intake not exceed 25 grams.

Claiming violations of their Eighth Amendment rights to be free of cruel and unusual punishment, the plaintiffs are being represented by the Weston A. Price Foundation, which opposes soy foods and has backed similar lawsuits in other states. The foundation claims that soy has replaced most of the meat and cheese in the inmates' diets and that soy flour or protein is now added to most baked goods. Too much soy, according to the foundation, can cause serious health problems, such as constipation alternating with diarrhea, vomiting, heart palpitations, rashes, acne, insomnia, panic attacks, depression, fatigue, weight gain, infections, and thyroid disease. Judge Harold Baker could apparently decide in September 2012 whether the case will proceed to trial. See *Weston A. Price Foundation Press Release*, October 25, 2011; *Chicago Tribune*, February 17, 2012.

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Mixed Rulings in PETA Litigation Against California "Happy Cows" Ad Campaign

According to news sources, a state court has ordered dairy farmers on the California Milk Advisory Board to answer questions about marketing the dairy industry in California. The order was reportedly entered in a lawsuit filed in June 2011 by People for the Ethical Treatment of Animals (PETA) alleging that the board's "Happy Cow" ads deceive the public by representing that California dairy products come from cows that are "happy," humanely treated, healthy, and comfortable. According to the animal rights' organization, the board lacks the evidence to substantiate the ad campaign. The court also apparently denied PETA's motion to subpoena confidential dairy-producer records relating to animal-welfare practices. The litigation is currently in discovery, and the next hearing has reportedly been scheduled for May 25, 2012. See *Capital Press*, February 9, 2012; *Merced Sun-Star*, February 16, 2012.

LEGAL LITERATURE

Food Advertising to Kids Deemed "Inherently Misleading"

In an article titled "Government Can Regulate Food Advertising to Children Because Cognitive Research Shows That It Is Inherently Misleading," two attorneys and a communications professor assert that the First Amendment is no bar to the regulation of "junk food" ads targeting children younger than 12 because they lack the ability to understand the advertisers' intent. Because children are unable to effectively comprehend advertising, according to the authors, any commercial messages directed toward them are "inevitably misleading." The research and article were supported in part by a Robert Wood Johnson Foundation grant.

The article first cites research about the amount of time children spend watching TV as well as "more than sixty published studies" purportedly linking TV exposure and obesity. It also discusses the numbers of "low-nutrient, calorie-dense" products advertised to children daily on TV and notes that the most heavily advertised food brands are also promoted online through advergames and other interactive techniques. Turning to First Amendment jurisprudence, the article then asks, "How is it that 'freedom of speech' came to include not only political commentary and artistic expression but also junk food ads?"

The authors contend that under the U.S. Supreme Court's "*Central Hudson* test," ads that promote illegal activity, are false or are actually or inherently misleading are exempt from First Amendment protection. According to the authors, studies show that children cannot reliably distinguish program content from commercial advertising until about age 4 or 5; children do not consistently demonstrate the knowledge that advertising messages

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are intended to sell products until about age 8; and “children generally lack effective understanding of advertising tactics such as exaggeration, embellishment, and ‘puffery’” until about age 11 or 12. Because the intended audience cannot properly comprehend food ads, the authors argue that government may ban advertising to children outright given that this lack of comprehension makes the ads inherently misleading.

They suggest that Congress “could bar all online junk food advergames aimed at children; the Federal Communications Commission could cap the number of junk food advertisements on children’s television programs; or the Federal Trade Commission could restrict the use of licensed characters in ads directed to children.” They conclude, “Any government efforts to regulate food advertising to children may face political hurdles, but the First Amendment should not pose an obstacle.” See *Health Affairs*, February 2012.

OTHER DEVELOPMENTS

Scientists Vie to Produce First Test-Tube Meat

Researchers presenting at the American Association for the Advancement of Science (AAAS) 2012 Annual Meeting in Vancouver, B.C., have announced two new ways to produce synthetic meat, significantly upping the ante in what AAAS describes as a potentially lucrative industry.

The first approach pioneered by Stanford University biochemist Patrick Brown reportedly uses plant material to create meat substitutes and may also serve as dairy products. Noting that grazing requires extensive land and energy use, Brown explained to AAAS attendees that “yields from the world’s four major food plant crops—corn, wheat, rice, and soybeans—already provide more than enough protein and amino acids for the world population.”

Meanwhile, a Dutch team led by Maastricht University Professor Mark Post has taken a different tack, “gradually transforming” cow stem cells “into tissues that resemble the skeletal muscle that makes up steak or hamburger.” The scientists apparently aim to produce the first lab-grown hamburger by the end of 2012 and anticipate that future applications will use approximately 40 percent less energy “than traditional livestock production.”

“If we can raise the efficiency from 15 to 50 percent by growing meat in the lab, that would be a tremendous leap forward,” said Post. Although the current iteration will most likely taste “bland,” the team aims to refine its methods toward replicating the meat components that give beef its actual flavor. To this end, an unnamed financier who donated approximately \$330,000 to the project has evidently pledged to contribute further funds once the proof-of-concept burger is unveiled. See *AAAS Press Release* and *Financial Times*, February 19, 2012.

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SCIENTIFIC/TECHNICAL ITEMS

Researchers Seek Phosphate Additive Labeling on Foods

German researchers claim that “elevated serum phosphate concentrations have recently been found to be correlated with mortality in patients with chronic renal failure, while high-normal serum phosphate concentrations have been found to be correlated with cardiovascular morbidity in the general population.” Eberhard Ritz, et al., “Phosphate Additives in Food—a Health Risk,” *Deutsches Ärzteblatt International*, 2012. Noting that naturally occurring phosphate in foods, “including meat, potatoes, bread, and other farinaceous products,” is not completely absorbed in the gastrointestinal tract and thereby poses less concern, the researchers contend that “inorganic phosphate in food additives is effectively absorbed and can measurably elevate the serum phosphate concentration in patients with CKD [chronic kidney disease].”

According to the authors, foods with large amounts of added phosphate include processed meats, canned fish, cheeses, baked goods, and cola beverages and other soft drinks. The ingredient is apparently added as a preservative, acidifying agent and buffer, and emulsifying agent, and to intensify flavors.

Because phosphate amounts are not required on food labels, consumers have no way to limit their phosphate intake, which the researchers contend should not exceed 1,000 mg daily. The principle pathophysiological effect of phosphate is apparently vascular damage, and the researchers concluded that foods with added phosphate “tend to be eaten by persons at the lower end of the socioeconomic scale, who consume more processed and ‘fast’ food.” While the researchers are uncertain whether “the association of a high serum phosphate concentration with increased morbidity and mortality reflects a direct toxic effect of phosphate or is rather due to pathological concentrations of the phosphate-regulating hormones FGF23 and klotho,” they suggest that “traffic-light” food labeling for the additive, public education about the additive’s potential effects, as well as “a quantitative restriction of phosphate additives” would be desirable.

FDA Expands Surveillance After Report on Arsenic in Rice

A recent study has reportedly detected inorganic arsenic (Asi) in organic brown rice syrup (OBRS), a prepared foods sweetener sometimes used in lieu of high-fructose corn syrup. Brian P. Jackson, et al., “Arsenic, Organic Foods, and Brown Rice Syrup,” *Environmental Health Perspectives*, February 2012. Researchers evidently sought to determine “the concentration and speciation of arsenic (As) in commercially available brown rice syrups, and in products containing OBRS including toddler formula, cereal/energy bars, and high energy foods used by endurance athletes.” Their results purportedly indicated

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that OBRS “can contain high concentrations of Asi and dimethylarsenate (DMA),” raising concerns about products such as organic toddler milk formula that use OBRS as a primary ingredient.

Meanwhile, the Food and Drug Administration (FDA) issued a February 17, 2012, [statement](#) pledging to expand “its surveillance activities” in response to the study’s claims. The agency has also commissioned its own research on arsenic in rice and rice products slated for completion in spring 2012.

“FDA is not aware of any brand of infant formula containing organic brown rice syrup (OBRS),” confirms the agency’s statement. “One brand of ‘toddler formula’ uses OBRS as a sweetener. This product is labeled for use in children older than 12 months, however the label also states that a health care professional should be consulted before using this product for infants under 12 months of age.”

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SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.

